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| APPLICATION NO.   | FILING DATE    | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|---|----------------|--------------------------|-------------------------|-----------------|
| 09/936,506  | 12/20/2001     | Herve Jean-Clement Coste | PF3623USW               | 6111            |
| 23347 75  | 590 12/01/2003 |                          | EXAM                    | INER            |
| DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY<br>GLAXOSMITHKLINE<br>FIVE MOORE DR., PO BOX 13398<br>RESEARCH TRIANGLE PARK, NC 27709-3398 |                |                          | WHITEMAN, BRIAN A       |                 |
|   |                |                          | ART UNIT                | PAPER NUMBER    |
|   |                |                          | 1635                    | 10              |
|   |                | •                        | DATE MAILED: 12/01/2003 | 3               |

Please find below and/or attached an Office communication concerning this application or proceeding.

| •   | Application No.         | Applicant(s)                                       |  |  |  |  |
|---|-------------------------|--|--|--|--|--|
|   | 09/936,506              | COSTE ET AL.                                       |  |  |  |  |
| Office Action Summary   | Examiner                | Art Unit   |  |  |  |  |
|   | Brian Whiteman          | 1635   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address Period for Reply  |                         |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |                         |  |  |  |  |  |
| 1) Responsive to communication(s) filed on  | ·                       |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ Th  | is action is non-final. |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |                         |  |  |  |  |  |
| Disposition of Claims   |                         |  |  |  |  |  |
| 4) Claim(s) 1-34 is/are pending in the application.   |                         |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                         |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |                         |  |  |  |  |  |
| 6) Claim(s) is/are rejected.  |                         |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |                         |  |  |  |  |  |
| 8) Claim(s) <u>1-34</u> are subject to restriction and/or election requirement.  Application Papers   |                         |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |                         |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |                         |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                         |  |  |  |  |  |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.   |                         |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |                         |  |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |                         |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |                         |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                         |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |                         |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |                         |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                         |  |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |                         |  |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |                         |  |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |                         |  |  |  |  |  |
| Attachment(s)   |                         |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informal P | (PTO-413) Paper No(s) Patent Application (PTO-152) |  |  |  |  |

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DETAILED ACTION

Claims 1-34 are pending.

The application does not comply with 37 CFR 1.821(d) because there are sequences in the specification with no SEQ ID NO:. The nucleotide sequences are listed in the CRF.

Applicants are advised to comply with the sequence compliance rules by amending the specification and claims with the corresponding SEQ ID NO: listed in the CRF to avoid an objection to the nucleotide sequences in a future office action.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, 27, 28, 29, 30, and 31, drawn to nucleic acids encoding Hsp70, vectors, host cells containing said nucleic acids and host cells containing said vectors, and a method of producing the polypeptide encoded by the DNA molecule set forth in claim 1 using an expression system.

Group II, claim(s) 18, 19, 21, 22, 23, 25, and 27, drawn to a DNA method of treating a deficiency in the expression of a polypeptide in a subject.

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Group III, claim(s) 20, 26, 27, 32, 33 and 34, drawn to a method of treating an infection in a subject comprising providing a subject with a vaccine.

Group IV, claim(s) 24, 25, and 27, drawn to an RNA method of treating a deficiency in the expression of a polypeptide in a subject.

Claim 25 link(s) inventions II and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 25.

Claim 27 link(s) inventions I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 27.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

37 CFR 1.475(b) states:

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"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process."

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

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"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product and method of using the product first mentioned in the claim and the International application does not comply with the requirements of unity of invention (Rules 13.1 and 13.2 and 13.3), they lack the same or corresponding special technical feature for the following reasons:

The technical feature linking group I-IV do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same corresponding or technical feature for the following reasons:

The claimed inventions of Group I-IV recite distinct materials and/or methods steps that are neither required nor recited in the other claimed inventions, and thus lack the same or corresponding technical feature for the following reasons:

The special technical feature of Group I is considered to be a nucleic acid and a method of producing the polypeptide encoded by the DNA molecule in claim 1 using an expression system.

The special technical feature of Group II is considered to be DNA method of treating a deficiency in the expression of a polypeptide in a subject.

The special technical feature of Group III is considered to be a vaccine.

The special technical feature of Group IV is considered to be an RNA method of treating a deficiency in the expression of a polypeptide in a subject.

Accordingly Groups I-IV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman Patent Examiner, Group 1635

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